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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/026,578

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Thomas Schmidt

VJP-1030-US

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35938 7590 09/03/2010

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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

09/03/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DOCKETING@BIOTECHNOLOGYLAWGROUP.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/026,578	<b>Applicant(s)</b> SCHMIDT, THOMAS	
	<b>Examiner</b> HOPE A. ROBINSON	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34,36,37,42-45 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,17,32-34,36,37,42-45 and 47-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/11/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's response to the Office Action mailed May 14, 2010 on June 6, 2010, is acknowledged.

### ***Claim Disposition***

2. Claims 1-34, 36-37, 42-45 and 47-51 are pending. Claims 16-17, 32-34, 36-37, 42-45 and 47-51 are under examination. Claims 1-15 and 18-31 are withdrawn as directed to a non-elected invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 16-17, 32-34, 36-37, 42-45 and 47-51 are rejected under 35 U.S.C. 103(a) as being obvious over Skerra et al. Biomolecular Engineering, 16, 1999, pages 79-86, cited on IDS filed 12/6/02) in view of Srisawat et al. (RNA, 2001, vol.7, pages 632-641).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

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in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

4. Skerra et al. teach a fusion protein comprising streptavidin binding domain such as Asn-Trp-Ser-His-Pro-Gln-Phe-Glu-Lys (page 81 of the reference) or Ala-Trp-Arg-His-Pro-Gln-Phe-Gly-Gly, see page 80 of the reference). On page 81 (right column) the reference discloses competitive binding with biotin. As the structure of the fusion protein is identical to the claimed structures, the fusion protein would inherently possess the binding affinity recited in the claims. Further, the recited distance is anticipated as it can be zero. Skerra et al. does not expressly teach a sequential arrangement of two modules, however, the such is within the skill of the art as increased numbers of tags would enhance the affinity. Moreover, Srisawat et al. teach use of multiple streptavidin affinity tags (see pages 632-634).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole a fusion protein comprising a streptavidin binding domain, because Skerra et al. teaches such a fusion protein and teaches a module that is SEQ ID NO:6 as recited in the claims, as well as the His-Pro-Gln structure required in a module. Although Skerra et al. does not expressly teach a sequential arrangement of said module, the art recognizes that affinity tags can be used in tandem and in multiples as evidenced by Srisawat. Moreover, the Supreme Court pointed out in *KSR*, “a patent composed of several elements is not proved obvious merely by demonstrating that each

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of its elements was, independently, known in the prior art.” *KSR*, 127 S. Ct. at 1741.

The Court thus reasoned that the analysis under 35 U.S.C. 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the “inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 1741. The Court further advised that “[a] person of ordinary skill is...a person of ordinary creativity, not an automation.” *Id.* at 1742.

Therefore, the claimed invention was obvious to make and use at the time the invention was made and was *prima facie* obvious.

### ***Response to Arguments***

5. The response filed has been received and entered. The rejections of record have been withdrawn, therefore, applicant’s comments will not be addressed herein as they are moot. Note that a new ground of rejection has been instituted under 35 USC 103(a) for the reasons set forth above.

### ***Conclusion***

6. No claims are presently allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652